Atty. Dkt. No. 071949-1328

Remarks

The present invention relates in part to assay devices comprising elements for the controlled flow, delivery, incubation, separation, washing and other steps of the assay process. The devices of the present invention can provide advantageous capture efficiencies and sensitivities for the assay of a plurality of target molecules.

Claims 1-7 are presently pending. A listing of all claims with appropriate status identifier is provided starting at page 2 of the present communication.

Applicant respectfully requests reconsideration of the claimed invention in view of the following remarks and terminal disclaimers provided herewith.

Telephone interview

Courtesies extended to Applicant's representative in the telephone interview conducted January 18,2006, are gratefully acknowledged. In substance, Applicant understands after the telephone interview that the alleged prior art due to Stöcker (see below) should be overcome by appropriate amendment provided herewith, and that currently pending obviousness-type double patenting rejections may be overcome by suitable terminal disclaimers. However, the Examiner indicated that additional search may be required before the case could be allowed.

Double Patenting – U.S. Patent No. 5,885,527

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,885,527. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent No. 6,019,944

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No.

6,019,944. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent No. 5,458,852

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,458,852. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent No. 5,922,615

The rejection of claims 1-2 and 6-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 5,922,615 is respectfully traversed. The present invention, as defined for example by Claim 1, is directed to an assay device comprising a nonpourous surface comprising one or more particles immobilized thereon, wherein the particles comprise receptors immobilized thereon, wherein the particles size range is from 1 nm to 5 μm. In contrast, each of the device claims and each of the method claims of the '615 patent requires a "porous member" defined therein (Col. 9, lines 41-43) as composed of a porous material used to provide solid phase support for the binding agent. Exemplary porous members of the '615 patent include membrane (e.g., nylon membrane) and filter. In view of the requirement for a porous member for the invention of the '615 patent, and the requirement for a nonpourous surface for the invention of the present claim, Applicant respectfully submits that the use of a nonporous surface in the claimed invention is not obvious over the use of a porous member. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the current rejection.

Double Patenting – U.S. Patent No. 6,271,040

Applicant assumes that U.S. Patent No. 6,771,040 recited in the Office Action (page 2, paragraph 4, line 4) is a typographical error that should properly recite U.S. Patent No. 6,271,040, filed July 30, 1997, with assignee Biosite, Inc.. Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-25 of U.S. Patent No. 6,271,040. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent No. 6,297,060

Applicant assumes that U.S. Patent No. 6,299,060 recited in the Office Action (page 2, paragraph 4, line 4) is a typographical error that should properly recite U.S. Patent No. 6,297,060, filed February 11, 1999, with assignee Biosite, Inc., which claims are directed to assay devices comprising a porous capture membrane in fluid-withdrawing contact with a nonabsorbent capillary network. The rejection of claims 1-2 and 6-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,297,060 is respectfully traversed. The present invention, as defined for example by Claim 1, is directed to an assay device comprising a nonpourous surface comprising one or more particles immobilized thereon, wherein the particles comprise receptors immobilized thereon, wherein the particles size range is from 1 nm to 5 μm. In contrast, the '060 patent requires in the single independent claims thereof a "porous member" defined therein (Col. 9, lines 45-47) as composed of a porous material used to provide solid phase support for the binding agent. In view of the requirement for a porous member for the invention of the '060 patent, and the requirement for a nonpourous surface for the invention of the present claim, Applicant respectfully submits that the use of a nonporous surface in the claimed invention is not obvious over the use of a porous member. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the current rejection.

Double Patenting – U.S. Patent No. 6,905,882

Claims 1-2 and 6-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,905,882. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent No. 6,767,510

Claims 1-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 and 25-37 of U.S. Patent No. 6,767,510. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent No. 6,156,270

Claims 1-7 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,156,270. Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Double Patenting – U.S. Patent Application No. 11/022,297

The provisional rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending U.S. Application No. 11/022,297 is respectfully traversed. No terminal disclaimer is procedurally required in a case where the provisional rejection involves two pending applications and where the rejection is the sole remaining issue in the case. See MPEP 804 (I)(B) (The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.") In the event that other rejections of the present claims are successfully overcome by the current communication, the current obviousness-type double patenting rejection would then be the sole remaining rejection, and withdrawal of the instant provisional rejection would be appropriate. Applicant respectfully requests deferral of response to the instant provisional rejection until allowable subject matter has been indicated.

Double Patenting – U.S. Patent Application No. 10/792,258

The provisional rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending U.S.

Application No. 10/792,258 is respectfully traversed. No terminal disclaimer is procedurally required in a case where the provisional rejection involves two pending applications and where the rejection is the sole remaining issue in the case. See MPEP 804 (I)(B) (The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.") In the event that other rejections of the present claims are successfully overcome by the current communication, the current obviousness-type double patenting rejection would then be the sole remaining rejection, and withdrawal of the instant provisional rejection would be appropriate. Applicant respectfully requests deferral of response to the instant provisional rejection until allowable subject matter has been indicated.

Double Patenting – U.S. Patent Application No. 09/982,629

The provisional rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74-93 of copending U.S. Application No. 09/982,629 is respectfully traversed. U.S. Application No. 09/982,629 issued as U.S. Patent No. 6,905,882 on June 14, 2005, and therefore is no longer pending. Concerning U.S. Patent No. 6,905,882, Applicant will file a suitable terminal disclaimer when allowable subject matter has been indicated.

Claim Rejection – 35 U.S.C. § 102

The rejection of claims 1-2 and 6-7 under 35 U.S.C. § 102(e) as allegedly being anticipated by Stöcker (U.S. Patent No. 4,647,543) is respectfully traversed.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP §2131.

The Examiner's characterization of the reference and its relationship to the claimed invention is not entirely clear. As best as Applicant can determine, the Examiner appears to be

analogizing the supports of Stöcker to particles in Applicant's claim ("Support 1(a) has been read on the claimed particles that immobilize the sample."; Office Action mailed November 1, 2005, page 4, lines 2-3.) However, Applicant's claim does not recite that particles immobilize sample. Rather, in certain claimed embodiments, particles comprising receptors that bind one or more target ligands are immobilized on a non-porous surface. *See, e.g.*, claim 1. The Examiner has not indicated which features of the Stöcker patent reference meet these various characteristics. This failure to properly consider and address the language of the present claims cannot establish a *prima facie* case of anticipation.

Moreover, the samples in Stöcker which the Examiner alleges are "particles" are actually fragments of a microscope slide cover slip that has been scored and broken into fragments. '543 patent, column 9, lines 36-39. The '543 patent discloses that relatively large (5 mm x 5 mm) frozen tissue specimens are mounted on standard cover slips which are then subdivided into fragments for attachment to a support. The Examiner has not indicated how it is believed the skilled artisan would consider such cover slip fragments to be "particles" as the Examiner asserts, particularly as that term is used in light of the present specification.

Nevertheless, in an effort to advance prosecution, Applicant has amended independent claim 1 herein to refer to particles having a size range from 1 nm to 5 μm. In contrast, the glass supports disclosed in the '543 patent are about 2 to 3 orders of magnitude larger in size to accommodate the large specimens and the physical nature of the manipulations employed in the '543 patent. *See, e.g.*, '543 patent, column 7, lines 37-39 and 49-50; see also column 7, lines 64-65, which indicate that even a "miniature frozen section" is on the order of 0.5 mm x 0.5 mm, *i.e.*, once a 5 mm x 5 mm frozen section has been divided into 100 portions.

Because the '543 patent does not disclose every limitation of the claimed invention, no *prima facie* case of anticipation has been established. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) be reconsidered and withdrawn.

Claim Rejection – 35 U.S.C. § 103

The rejection of claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over Stöcker is respectfully traversed. In order to maintain a rejection for obviousness under 35 U.S.C. § 103(a) is must be shown that (a) there is some suggestion, either in the reference or in the knowledge of one of ordinary skill in the art, to modify or combine the reference teachings; (b) the alleged prior art teachs or suggests all of the claim limitations; and (c) there is reasonable expectation of success. In view of the particle size limitation of Claim 1, as amended, Stöcker does not teach all of the claim limitations of the present invention. Accordingly, the present invention cannot be obvious over Stöcker, and Applicant respectfully requests reconsideration and withdrawal of the current rejection.

Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Atty. Dkt. No. 071949-1328

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 01/27/2006

By

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